PCT/EP2003/009750

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P 63863PC HJW/hör	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP2003/009750	International filing date (*day/month/year*) 02 September 2003 (02.09.2003)	Priority date (*day/month/year*) 11 September 2002 (11.09.2002)
International Patent Classification (IPC) or national classification and IPC A61K 39/35		
Applicant FRESENIUS KABI DEUTSCHLAND GMBH		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
20 January 2004 (20.01.2004)	07 July 2004 (07.07.2004)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.
PCT/EP2003/009750

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:
pages 1-28, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages 1-14, filed with the letter of 16 June 2004 (16.06.2004)

☒ the drawings:
pages 1/8-8/8, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:
☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.
PCT/EP2003/009750

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 1-14

because:

☒ the said international application, or the said claims Nos. 1-14 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

See Supplemental Sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box III

Claims 1 to 14 relate to subject matter which, in the opinion of this Authority, falls under PCT Rule 67.1(iv). Consequently no expert opinion has been established regarding the industrial applicability of the subject matter of these claims (PCT Article 34(4)(a)(i)).

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-14	YES
	Claims		NO
Inventive step (IS)	Claims	1-14	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-14?	YES
	Claims		NO

2. Citations and explanations

1. Reference is made to the following documents:

D1: WO-A-9730148
D2: US-A-4261973
D3: WO-A-02080979
D4: WO-A-03074087

2.1 The subject matter of claim 1 is novel over the prior art (PCT Article 33(2)) because none of the cited documents disclose the combination of technical features proposed in claim 1.

2.2 The same applies to dependent claims 2 to 14 (PCT Article 33(2)).

3.1 Document D2 discloses a process for suppressing IgE immune responses using an allergen-polymer conjugate in which the polymer and the allergen are covalently coupled (column 2, line 9 to column 3, line 58; example 1; claim 1). The conjugate uses various polymers, including PEG. The subject matter of claim 1 differs from that of D1 in that hydroxyalkyl starch is used in the conjugate. The technical problem addressed is that of providing a polymer for conjugation that can

be broken down *in vivo*. Document D1 discloses conjugates of proteins and polymers including (*inter alia*) hydroxyethyl or hydroxypropyl starch. The conjugation process reduces the allergenicity of the proteins, but is not intended for a use in the context of immunotherapy. There is no mention of the biodegradability of the starch, and therefore a person skilled in the art would have no reason to combine the technical teachings of D1 and D2 when attempting to solve the aforementioned problem. The solution proposed in claim 1 is therefore inventive (PCT Article 33(3)).

3.2 The same applies to claims 2 to 14, which are dependent on claim 1 (PCT Article 33(3)).

4. The PCT Contracting States do not have uniform criteria against which the industrial applicability of claims 11 to 17 can be assessed. Patentability may depend on the wording of the claims. For example, the European Patent Office does not recognise the industrial applicability of claims to the medical use of a compound. It may, however, allow claims to the first medical use of a known compound or to the use of such a compound in the preparation of a drug for a new medical application.

5.1 Claim 4 uses the term "preferably". Such terms do not limit the scope of a claim, and indeed any technical feature qualified by such a term is regarded as entirely optional (see the PCT Examination Guidelines, paragraph III-4.6). The technical feature in question should have been either deleted or made the subject of a separate dependent claim.

5.2 Claim 10 uses the term "specific immunotherapy",

which is unrelated to the claims to which claim 10 refers back. This creates a problem of clarity (PCT Article 6). The term should have been changed to "hyposensibilisation".

6. Certain published documents (PCT Rule 70.10):

If the priority claim of the present application is found to be invalid, document D3 will become relevant for the assessment of novelty and inventive step (PCT Article 33(2) and (3)), and when the application enters the regional phase both D3 and D4 will be relevant for the assessment of novelty.